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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,760	07/31/2001	Paul Douglas Scotti	514274-2001	6462

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745 Fifth Avenue
New York, NY 10151

EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/868,760

Applicant(s)

SCOTTI ET AL.

Examiner

Yong D Pak

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-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/10/2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,10,12,13 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,10,12,13 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on November 10, 2003, amending claims 9 and 25, canceling claims 1-8, 11 and 14-24, has been entered.

Claims 9, 10, 12, 13 and 25 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 10, 12-13 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 is drawn to serine protease inhibitor fragments. Therefore, these claims are drawn to a genus of polypeptides with any structure. The genus comprising SEQ ID NO:1-5 or portions of SEQ ID NO:7 is a large variable genus with the potentiality of encompassing many different polypeptides having serine protease inhibitor activity. The peptides of SEQ ID NO:1-5 are generated by chemical and enzymatic cleavage and therefore is not representative of fragments having full activity (specification, page 16). Therefore, many structurally unrelated DNA are encompassed within the scope of these claims. The specification fails to describe any other representative species by any identifying characteristics or properties other than being comprised of the fragments of

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SEQ ID NO:1-5 and fails to provide any structure: function correlation present in all members of the claimed genus.

Claim 10 is drawn to polypeptides that are functionally equivalent variants of SEQ ID NO:7. Therefore, the claims are drawn to a large variable genus of polypeptides having serine protease inhibitory activity having an insufficient limitation on structure and derived from any source. The specification only describes the serine protease inhibitor of SEQ ID NO:7 and does not describe serine protease inhibitors from any source.

Claim 25 is drawn to a wide genus of polypeptides having serine protease inhibitory activity with an insufficient limitation on structure. Even though the claim is limited to a serine protease inhibitor from *Perna canaliculus* with a molecular weight of 75kDa, the genus encompasses many different serine protease inhibitors. The specification only describes a serine protease inhibitor of SEQ ID NO:7 and does not describe other inhibitors derived from *P. canaliculus*. The source of the inhibitor and the apparent molecular weight is not enough to describe the polypeptides encompassed in the claim.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 9, 10, 12-13 and 25.

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Claim 9, 10 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a serine protease of SEQ ID:7, does not reasonably provide enablement for fragments of SEQ ID NO:7 with unlimited structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to polypeptides having unlimited structure. The claims broadly encompass any fragments of SEQ ID NO:7 and any serine protease inhibitors. The claims also encompass polypeptides having very low structural similarity to the serine protease inhibitor of SEQ ID NO:7. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The quantity of experimentation in this area is extremely large since there is significant variability in the structure of the polypeptides. It would require many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

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The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its structure. Due to the insufficient teaching of the structure, it is entirely unpredictable what structure will be found for the broadly encompassed polypeptides. The prior art does not resolve this ambiguity, since no prior art teaches how to field for serine protease inhibitors from such little information on its structure.

Further, despite knowledge in the art for isolating polypeptides, the specification fails to provide guidance regarding which amino acids of SEQ ID NO:7 are required to impart a polypeptide as a serine protease inhibitor. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity are limited in any protein and the result of such modifications is unpredictable.

The specification, which places weak limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does not establish: (A) regions of the serine protease inhibitor structure which may be modified without effecting its inhibitory activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

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Therefore, one of ordinary skill would require guidance in order to use polynucleotides encoding polypeptides having unlimited structure in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is drawn to a polypeptide having serine protease inhibitory activity. The claims are confusing because a polynucleotide that hybridizes to the polynucleotide encoding SEQ ID NO:7 can not encode a polypeptide having serine protease inhibiting activity.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-746-7240 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

December 22, 2003



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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